

Remarks

Claims 1-6 and 8-52 are pending. Claims 23-27 and 32-52 are withdrawn from consideration. Claims 1-6, 8-22 and 28-31 are presently under examination. Claims 1-6, 8-10, 12-14 and 17-18 have been amended. No new matter has been added.

Drawings

Applicants reiterate that formal drawings will be required in this case when the application is allowed.

Section 102 Rejections

The Examiner has maintained the rejection of Claims 1-6, 8, 11, 13-15, 17-19, 21, 22 and 28-31 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,792,456 ("Yelton"). The Examiner has also rejected the claims under Section 102 as anticipated by Gundel (WO 93/02702) and Suzuki (JP 403128330A). These rejections are respectfully traversed.

The Examiner alleges that Yelton teaches a mutated BR96 antibody lacking an Fc region and, therefore, lacks the CH2 domain in its entirety, thus meeting the claim limitations. Gundel and Suzuki are similarly cited for their lack of a CH2 domain which the Examiner alleges anticipates the claims. The claims have been amended to clarify that the present invention is directed to an antibody having a CH2 domain present wherein the claimed amino acids of the CH2 region have been modified to alter the toxicity of the administered immunoglobulin. As none of the cited references disclose a CH2 region, they do not anticipate the claimed invention.

Accordingly, withdrawal of the rejections under Section 102 is appropriate and is respectfully requested.

Section 112, Second Paragraph Rejections

The Examiner has rejected Claims 1-6, 8-22 and 28-31 under 35 U.S.C. §112, Second paragraph, as allegedly being indefinite. These rejections are respectfully traversed.

The claims have been amended so that "inhibiting" is used consistently throughout. With respect to the rejection that it is unclear what amino acids 231-238 and 310-331 refer to, Applicants respectfully submit that these amino acids refer generically to the CH2 domain of an immunoglobulin molecule. Applicants have amended the claims to address all other Section 112, second paragraph, rejections.

Accordingly, withdrawal of the rejections under Section 112, second paragraph, is appropriate and is respectfully requested.

Section 112, First Paragraph Rejection (New Matter)

The Examiner has rejected Claims 1-6, 8-22 and 28-31 under 35 U.S.C. §112, First Paragraph, as containing new matter. The Examiner alleges that "domains" is used in the definition of "multiple toxicity associated domains" whereas "regions" is used in the claims. This rejection is respectfully traversed.

Applicants point out that in both cases reference is being made to amino acids 231-238 and 310-331 of the immunoglobulin. A proper reading of the entire specification makes clear that these regions are present in the CH2 domain. This is also supported by the literature. Clearly, no new matter has been added. Rather, inclusion of these sequences into the claims is done merely to clarify that those are the amino acids which, if mutated, result in reduced toxicity of the administered immunoglobulin to the subject.

Accordingly, withdrawal of this new matter rejection under Section 112, first paragraph, is appropriate and is respectfully requested.

The Examiner has also maintained the rejection of Claims 16, 8-12, 15, 16, 19, 20 and 28-31 under 35 U.S.C. §112, First Paragraph, as lacking enablement. This rejection is respectfully traversed.

The Examiner alleges that that the claimed subject matter is not enabled by the Example shown in the specification. Applicants point out, however, that specific amino acids regions are provided for in the claims which, if mutated, result in reduced toxicity of the administered immunoglobulin to the subject. Clearly, one of skill in the art, working from the teachings of the present specification, would be able to use art-recognized mutagenesis techniques to determine which amino acid mutations would be appropriate within the claimed regions in order to produce an immunoglobulin which results in lower toxicity as compared to the same immunoglobulin without such mutations. Further, the claimed amino acid regions do not apply only to BR96, but to other immunoglobulins, for example IgG1. Thus, Applicants respectfully submit that the scope of the present claims is supported by the teachings of the present specification.

Accordingly, withdrawal of the enablement rejections under Section 112, first paragraph, is appropriate and is respectfully requested.


Conclusion

In view of the amendments and remarks above, Applicants submit that the claims are in condition for allowance and favorable action is therefore respectfully requested.

Please direct any questions regarding this reply to the undersigned attorney.

Respectfully submitted,

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Date: December 2, 2004